SUMMARY OF THE
SIXTH INTERIM MEETING OF THE
NATIONAL ENVIRONMENTAL LABORATORY ACCREDITATION CONFERENCE
OCTOBER 31 - NOVEMBER 3, 2000

INTRODUCTION

The National Environmental Laboratory Accreditation Conference (NELAC) held its Sixth Interim Meeting, NELAC 6i, October 31 - November 3, 2000, at the Riviera Hotel in Las Vegas, NV. The meeting was sponsored by the U.S. Environmental Protection Agency (EPA). Approximately 210 individuals participated.

OPENING PLENARY SESSION

Ms. Jeanne Hankins, NELAC Director, welcomed participants to the opening plenary session and introduced members of the NELAC Board of Directors (BoD): Dr. Charles Brokopp (Chair), Ms. Sylvia Labie (Chair-Elect), Dr. James Pearson (Past Chair), Ms. Jeanne Hankins (Director), and Dr. Stephen Billets (Executive Secretary, Acting). She also introduced the committee chairs: Ms. Janet Cruse (Accreditation Process), Mr. John Anderson (Accrediting Authority), Mr. Daniel Bivins (Field Activities), Mr. William Ingersoll (On-site Assessment), Ms. Barbara Burmeister (Proficiency Testing), Dr. Kenneth Jackson (Program Policy and Structure), Mr. Scott Siders (Quality Systems), Dr. Carl Kircher (Regulatory Coordination), Ms. Margaret Prevost (Membership and Outreach), Dr. James Pearson (Nominating), Mr. Matthew Caruso (National Database), and Ms. Sylvia Labie (Transition).

Ms. Hankins then introduced Dr. John Lyon, Director of EPA's National Exposure Research Laboratory's (NERL) Environmental Sciences Division. Dr. Lyon welcomed participants and provided background on the federal government's environmental laboratory in Las Vegas. The facility has been an environmental laboratory since the 1970's and has a long history of hosting people to discuss environmental issues. He also provided a brochure describing the laboratory's history and work. Dr. Lyon said that he is pleased to be a part of the work of national environmental laboratory accreditation. He said that he is excited by the opportunity to host NELAC and hopes to help forge an exciting future.

Ms. Hankins reviewed the schedule for the week including committee sessions and the closing plenary session. She announced that there would be presentations given by the National Environmental Laboratory Accreditation Program (NELAP) Accrediting Authorities and the Accrediting Authority Review Board (AARB). On Wednesday evening, there will be a special session for states and other interested parties regarding proficiency testing (PT) data management systems, hosted by Mr. Tom Coyner from Analytical Products Group and Mr. Chuck Wibby from Environmental Resource Associates. On Thursday, the Environmental Laboratory Advisory Board (ELAB) open forum will take place and all participants are encouraged to attend. The ELAB meeting is on Friday, November 3, 2000.

Remarks from the Chair

Dr. Charles Brokopp began his remarks by recognizing the number of people actively involved in NELAC and the numerous hours spent in developing the program. He thanked everyone who has helped to develop the standards. Dr. Brokopp also recognized the support and leadership received from EPA and said that it is nice to have a partner to work with on this program. During the past couple of years, a number of questions have been raised on how to move forward with the national laboratory accreditation program. He stated that the standards have been established and are being implemented by the accrediting authorities. By January 1, 2001, NELAC will be able to recognize its first accredited laboratories. The process has not been without stumbling blocks. The conference has already been faced with issues about assessor consistency, reciprocity, and proficiency testing and additional issues are anticipated. For example, there are issues related to the publication of the NELAC Standard around International Organization for Standardization (ISO) standards and ongoing support for NELAC. Dr. Brokopp stated a goal for NELAC is to increase the number of accrediting authorities in the program. He encouraged attendees to ask questions and give input in order to further the process.

NELAP Accrediting Authorities

Mr. Dave Mendenhall, from the Utah Department of Health, gave a presentation for the NELAC Accrediting Authority workgroup. He began with an overview of what the workgroup is and what it does. He then summarized the recent decisions (since July 11, 2000) made by the NELAP Accrediting Authorities in their biweekly teleconference meetings. This background information and summary of decisions is available on the NELAC Website at <http://www.epa.gov/ttn/nelac/aarelated.html>.

Members of the Accrediting Authority workgroup are the NELAP-recognized accrediting authorities and currently include: California, Florida, Illinois, Kansas, Louisiana, New Hampshire, New Jersey, New York, Oregon, Pennsylvania, and Utah. The Accrediting Authority workgroup agreed on August 8, 2000, that none of the accrediting authorities would have trouble recognizing interim accreditation from another accrediting authority. A poll of state programs found that five non-NELAP-accredited states have also agreed to recognize NELAP-accredited laboratories: Georgia, Maine, Vermont, Washington, and West Virginia.

Accrediting Authority Review Board

Ms. Judith Duncan, from the Oklahoma Department of Environmental Quality, spoke on behalf of Mr. George Mills, chair of the Accrediting Authority Review Board. She said that the AARB will review their annual report and minutes from June 2000, discuss a potential change in the AARB's charter, and discuss possible activities for the coming year in their meeting on Thursday, November 2, 2000. Additional discussion items include: review of newly completed accrediting authority reviews of accreditation applications, review of NELAP procedures for dealing with accrediting authority reviews, the potential for recognition of secondary accrediting authorities, and a mechanism for deal with issues and complaints raised by laboratories. Ms. Duncan encouraged input from stakeholders on these issues.

Keynote Address

Mr. Henry Longest, II, Deputy Administrator of EPA's Office of Research and Development, delivered the keynote address. Mr. Longest congratulated NELAC participants as they develop a working national environmental laboratory accreditation program. He said that NELAC should be proud of the fact that 11 states are recognized as accrediting authorities and that over 1,000 laboratories have applied for accreditation. He said that he looks forward to January 2001 when the first class of accredited laboratories will graduate.

Mr. Longest spoke about the status of the NELAC program within EPA. He said that the Quality Assurance Division has been transferred to the Office of Environmental Information and thanked Ms. Nancy Wentworth and her staff for all the work they have done to help the NELAC program. He expressed his confidence that they will continue to play an active role in the various NELAC committees now that the Office of Research and Development's (ORD) support to NELAC is through the National Exposure Research Laboratory (NERL) at Las Vegas, Nevada.

He noted that NERL-LV has many years of experience in environmental monitoring and laboratory evaluation through their work in supporting the agency's programs under the Resource Conservation and Recovery Act (RCRA) and Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA, or Superfund). They understand and are committed to Performance-Based Measurement Systems (PBMS) and the need for EPA and NELAC to change their approach in order to foster innovation and acceptance of new monitoring technologies.

Mr. Longest then noted key NELAC players from EPA:

- Dr. John Lyon, the Director of NERL-LV and of the NELAP effort.
- Ms. Jeanne Hankins, the NELAC Executive Director, who is now part of the NERL-LV operation while physically residing in RTP, NC.
- Dr. Steven Billets, the Designated Federal Official for ELAB, also assisting in the NELAP effort.
- Mr. David Friedman, the headquarters policy coordinator for the program and active participant in NELAC and in ELAB committees and workgroups.

Mr. Longest said that although ORD's budget has not been officially approved yet, their plan is to put $500,000 into this effort in fiscal year 2001, in addition to their staff support. He said that the EPA Regions have done a tremendous job of supporting the accreditation process, and he anticipates that they will continue their support.

Mr. Longest discussed some of the important issues related to laboratory accreditation. He said that the Intertek Testing Services prosecution highlights the critical need for a high quality, very thorough accreditation process with respect to both the accrediting authorities as well as the laboratories themselves. He emphasized the importance of NELAC adopting the ISO 17025 PBMS approach in its program and move away from the "method based" program approach. As a recent decision in EPA enforcement case pointed out, even in the effluent guidelines programs

where use of EPA methods are mandated, the court will consider compliance monitoring data gathered using non-EPA methods. Therefore, the NELAC program must address all the work that a laboratory conducts to ensure that it is of known and documented quality.

He then discussed efforts to further the adoption of PBMS and resolve outstanding issues. He said that last year, after the discussions at the NELAC and Waste Testing and Quality Assurance (WTQA) meetings, American Society for Testing and Materials (ASTM) Committee D-34 initiated a substantial effort to develop a new standard to address the issue of what metadata is needed to ensure the scientific and, therefore, the legal defensibility of analytical results. This effort should go a long way to helping resolve what has been a major issue with regard to what constitutes scientifically defensible data. Mr. Longest urged participants to listen carefully to the presentations given about the effort and to do all they can to help ASTM develop the standard and to adopt it into the NELAC program.

Mr. Longest said that last summer, Dr. Norine Noonan and he challenged the BoD to not wait until EPA has fully implemented PBMS before moving forward, but to move forward as soon as possible. In response to the BoD's request, ELAB recently looked at the history of the PBMS program and the concerns and ideas of all parties involved (EPA Program Offices, States, and the private sector). Then they developed an approach to guide NELAC in implementing the PBMS approach in its standards. Mr. Longest urged participants to carefully consider ELAB's report and to develop an approach to implementing PBMS in the NELAC program as soon as possible.

Regarding EPA's PBMS activities, Mr. Longest informed participants that EPA is working with their Office of Enforcement to finalize a training program for the enforcement and compliance officers. Within the next few months they will pilot test the approach that was laid out in the draft training program. They are also working with the Program Office senior management to move the program forward.

Mr. Longest commended the initiative taken by the BoD and members of ELAB who recently visited with the Office of Water in order to build support within the Program Offices. He said that it was an excellent idea and thanked them for the effort. In addition, he said that ORD is very happy to see the overtures that NELAC has made to the state environmental leadership through the Environmental Council of the States (ECOS). Some of the EPA and state agencies are not even aware of NELAC. He said that such activities will go a long way toward retaining and building support within the agency and states for the NELAC program.

Mr. Longest then noted challenges for NELAC in 2001. The first challenge was to increase the number of accrediting authorities. He said that for the program to be truly successful, we need to have all, or almost all, the states become accrediting authorities. The second challenge was to improve the quality and consistency of the accreditation process. This includes training of inspectors to ensure competency and consistency, and oversight of the inspection and accreditation process to ensure credibility. The third challenge was to increase the number of accredited laboratories. He said that we need to look at the suitability of the NELAC program with regard to small laboratories such as in-house process control laboratories that conduct waste water and drinking water tests. He also said that the method-by-method, very prescriptive approach embodied in the current NELAC standards may pose too big a burden to such

laboratories. Fourth, he challenged NELAC to continue to incorporate PBMS concepts into the NELAC program. The recent ruling, from the Federal Court in Pennsylvania in the Allegheny Ludlum case, mentioned earlier, strengthens the concept that good data will be acceptable in court even if it is not generated using "approved" methods. The focus of laboratory work, and therefore of the accreditation process, thus should be on ensuring that the laboratory is generating quality data, not that they are following a particular method. The NELAC standards must do all they can to promote use of new, less costly monitoring technologies. The NELAC program must also adapt to the fact that, in the future, more and more of the testing may move away from the laboratory and into the actual monitoring location. Mr. Longest said that he knows NELAC is actively working to develop standards for field work and encouraged the conference to continue this effort. The fifth, and final challenge, was to work to improve reciprocity between the states in order to reduce costs to the laboratory community.

In closing, Mr. Longest noted that tremendous progress has been made by NELAC toward improving the quality of data from our nation's environmental laboratories. He told participants that they can be proud of the success they have had to date. He said that ORD is also very gratified to see the progress that NELAC is making in responding to his request, last year, to reduce the administrative support burden on EPA. However, we cannot rest on our laurels. He said that we need to move forward to improve and expand the program to all the states and to the whole environmental laboratory community. Mr Longest stated that we need to work to make the program not only cost-effective, but one which has a very, very high level of credibility. The quality of the accreditation process must be one with which the public can have complete confidence. Mr. Longest said that he, his staff, and he is certain the rest of EPA, will continue to work with the NELAC community to make that vision a reality.

Performance Based Measurement Systems

Members of ELAB's subcommittee for Performance Based Measurement Systems (PBMS) gave presentations on *PBMS Activities and Perspectives*. Copies of the presentation were distributed to participants during the opening plenary (see Attachment A).

Mr. Jerry Parr, from Catalyst Information Resources, presented *EPA Activities to Establish PBMS*. Ms. Anne Marie Allen, from the Massachusetts Department of Environmental Protection, presented *A State Perspective*. Dr. Harry Gearhart, from DuPont, presented *A Perspective from Industry*. Ms. Deb Loring, from Severn Trent Laboratories, presented *A Laboratory Perspective*. Ms. Elaine LeMoine, from Perkin-Elmer Instruments, presented *An Instrument Manufacturer's Perspective*. The general consensus of the speakers was that the time is now for PBMS.

Dr. Gearhart then presented a *PBMS Implementation Strawmodel* (see Attachment B). The strawmodel presentation was included in participant packets. Dr. Gearhart said that the summary document would be distributed at the ELAB open meeting on Thursday, November 2, 2000.

Open Discussion

Participants were then invited to participate in an open discussion of the PBMS issue. One participant suggested that NELAC classify types of methods and list items which must be checked. He gave the following as an example of method classification:

- Class 1 – minor modifications of recognized EPA methods
- Class 2 – published methods (in scientific, peer-reviewed journals)
- Class 3 – unpublished methods (developed by the company itself)
- Class 4 – new technology (which have gone through an EPA verification program)

An industry participant said that it would be valuable to have a central database which contained information to help evaluate the performance of methods. This would help prevent "reinventing the wheel" and also give information about matrix effects. A subcommittee member noted that there is a concurrent ASTM effort to evaluate existing data. The Department of Defense also has efforts underway to compile method performance data.

A state participant said that the State of Florida is attempting to implement PBMS. She said that the elements are already in place in the NELAC Standard to implement PBMS on a laboratory level. Her concern is not with the laboratories, but with the data users (permittees, programs, etc.). She questioned whether NELAC is not be the proper forum to address the education of data users.

A consultant said that NELAC must consider a way of allowing new methods for emergency situations. He said that the environmental industry has a lot of "old-timers" who do not like change. We have to educate these people (users, assessors, regulators) to help them understand the quality systems approach.

A state participant said that NELAC needs to try to get the environmentalist community involved in accreditation. He pointed out that there is a large distrust issue to deal with. He also commented that there is need for an inexpensive data validation package and said that NELAC must also address surveillance issues.

Mr. Scott Siders, chair of the NELAC Quality Systems Committee, said that the Quality Systems Committee has many issues to address and needs specific language to help them integrate PBMS into Chapter 5. He also requested help from the ELAB PBMS subcommittee.

A participant from a commercial laboratory reiterated the trust issue. He suggested that perhaps the NELAP National Database would be a good place to store information which could be displayed on the internet, in order to build trust.

A regional EPA participant asked what current level of support NELAC has from other EPA programs. Mr. Longest said that ORD is currently working on getting feedback, but there is nothing to report now; he stressed that support from the EPA Program Offices is important.

A state participant from California said that they need a definite measure of data quality characteristics of the method from which the data is generated (more than just the standard deviation). This needs to be included in the laboratory report so the accrediting authorities know the comparability of the method.

A state participant from Colorado said that they need a definite measurement of data quality characteristics so that regulators (other than EPA) can be convinced to use the method that are not EPA-approved..

A state participant from Oregon reminded the conference not to forget the other disciplines (e.g., biology, microbiology, radiochemistry). She reminded participants that NELAP is not just for chemistry.

A participant from a commercial laboratory voiced concern about expected difficulty in convincing people to use PBMS. He said that the endorsement of EPA is important, but to be successful, education is the most important factor. He also agreed that it is important to create method categories, as previously suggested.

A participant from another commercial laboratory asked the conference to consider the definition of "modified method" and asked that they be specific in addressing modified methods in the method categories. He said that this is especially important for data users and regulators.

ADJOURNMENT OF OPENING PLENARY SESSION

Ms. Jeanne Hankins closed the plenary session and invited participants to continue these discussions at the ELAB open forum on Thursday, November 2, 2000.

COMMITTEE WORKING SESSIONS

Following the opening plenary session, concurrent working sessions were held for all 12 standing, administrative, and *ad hoc* committees, and the Accrediting Authority Review Board. Progress made by each committee, as well as principal unresolved issues (and expected time frames for addressing them) were presented in the closing plenary session. In keeping with the goals established for the national NELAC meetings, all working sessions were of an open-forum format in which all attendees were encouraged to participate.

Some important common deadlines were presented by each of the committee chairs:

- January 19, 2001. Last day for participants to submit comments for committees' consideration. Comments will be addressed in the order received.
- March 19, 2001. Committees should submit final version of proposed changes for the Seventh NELAC Annual Meeting (NELAC 7).
- April 6, 2001. Date for publication of proposed changes on the NELAC Website.
- May 22-25, 2001. Discussion, final modifications, and vote on proposed changes at NELAC 7.

Program Policy and Structure – Chair: Dr. Ken Jackson

The only agenda item for the committee was the NELAP Scope of Accreditation. Dr. Jackson said that at the Sixth NELAC Annual Meeting (NELAC 6) in Williamsburg, VA, the committee came away with the impression that there was a need to change from "program-method-analyte." During their session at this conference, the committee presented participants with possible models for the Scope of Accreditation. They also discussed definitions of "matrix," "method," and "analyte/analyte group."

For "matrix," the committee intends to propose the following: Potable Water, Non-Potable Water, Solid & Chemical Waste, and Air. Although not in the current scope of accreditation, the committee is considering adding biological tissues. Also, "Air" may be too general a term for matrix. "Method" will be re-defined for more flexibility. The inclusion of "analyte group" may help to facilitate reciprocity, but the committee believes that the laboratory must demonstrate its ability to determine every analyte in the group (through demonstration of capability, method detection limits, on-going quality control, and proficiency tests where available).

Dr. Jackson said that the committee received useful comments and has a sense of direction, but needs more feedback from participants. Therefore, during the closing session, he took a strawpoll to see which model the conference preferred. Three options were voted on:

- Matrix-Method-Analyte/Analyte Group
- Technology-Matrix-Method-Analyte/Analyte Group
- Technology-Matrix-Analyte/Analyte Group

The results of the strawpoll are as follows. The state and federal agencies were evenly divided between Options 2 and 3, with preference over Option 1. The laboratories preferred Option 3 over Option 2, and had only one vote for Option 1. A representative from EPA stated that EPA cannot live with Option 3, because federal regulations require accreditation by method; however, another representative from EPA voiced disagreement.

Dr. Jackson said that the committee's goal is to select one model and develop appropriate language for Chapter 1 based on this model by March 19, 2001.

Proficiency Testing – Chair: Ms. Barbara Burmeister

A major highlight of the committee meeting was that it sponsored a meeting of stakeholders to open dialog between PT providers, accrediting authorities, and laboratories. During the committee session, reports were given from three subcommittee working groups on:

- Data Reporting Issues (especially for non-detects)
- Quick Response/Corrective Action Studies
- Report Format

Ms. Burmeister said that the Proficiency Testing Committee is developing a standardized list of method codes. They discussed a potential change to the PT Field of Testing and may possibly delete "program" and add "analyte group." The committee needs comments especially from accrediting authorities and federal agencies. Ms. Burmeister said that the Proficiency Testing Committee will continue to work on this issue with the Program Policy and Structure Committee. Unresolved issues include the definition of "analyte group" for proficiency testing, scoring criteria for analyte group, and representative analytes within an analyte group.

Future plans are to write a Frequently Asked Question (FAQ) document for how laboratories report non-detected analytes to PT providers and PT providers report to accrediting authorities (by 12/15/00), propose language to allow limited use of PT samples for corrective action purposes (by 3/19/01), propose language for uniform report format (by 3/19/01), evaluate the current PT Field of Testing for a potential change (by 3/19/01), and develop standardized method codes (by 5/22/01).

On-site Assessment – Chair: Mr. William Ingersoll

The On-site Assessment Committee presented the following training standards for comment:

- Appendix A. Basic NELAC Assessor Training Student Manual Draft Outline
- Appendix B-1. Standards for Technical Training Courses for Assessors
- Appendix B-2. Standard for Critical Performance Elements of Test Methods

Mr. Ingersoll said that these appendices were included in participant packets and the committee welcomes any comments. The committee also proposed changes to Chapter 3 for additional clarification of the language.

Unresolved issues include: uniform and consistent on-site assessments (committee will work with accrediting authorities and the Transition Committee), evaluation of assessor training based on standard, "feedback" mechanisms to evaluate on-site assessments, and maximum time allowed to complete assessor training. Mr. Ingersoll said that the only "feedback" mechanism right now is the assessment appraisal form. Some possible options include a telephone "hotline" or a web page questionnaire for laboratories. The committee hopes to have some action on these issues by March 19, 2001.

Future plans are to incorporate proposed changes into Chapter 3 and the training appendices by March 19, 2001.

Accreditation Process – Chair: Ms. Janet Cruse

The committee is proposing the addition of a "Flow Chart for NELAP Accreditation of a Laboratory." Ms. Cruse said that the flow chart is intended to guide those interested parties through the accreditation process. All elements must be met: the order in which all elements are met shall be determined by each accrediting authority.

An unresolved issue is the use of the term "may" versus "shall" in determining whether the on-site assessment consists of all of the Fields of Testing and/or methods for which the laboratory wants to obtain accreditation (Section 4.1.2). Ms. Cruse said that the committee needs to clarify with Chapter 3 their intent. (Action by 3/19/01.)

Future plans include: editorial changes to Chapter 4 for clarification (by 3/19/01), review of Section 4.0 relative to mobile laboratory operations (by 3/19/01), and continuation of cooperation with Field Activities Committee to ensure consistency with existing the NELAC Standard (ongoing).

Quality Systems – Chair: Mr. Scott Siders

Mr. Siders said that most of the committee's issues came out of the NELAC 6 meeting. Substantive issues include: ISO/IEC 17025 integration into NELAC Chapter 5 (first priority), ELAB comments on Section D.1, proposed changes to Section D.3, and the PBMS strawmodel (new issue from this meeting). The proposed changes from ELAB on Section D.1 relate to method blank criteria and the number of compounds to spike into laboratory control samples and matrix spikes.

Another unresolved issue is related to asbestos testing. The American Industrial Hygiene Association (AIHA) expressed concern about NELAC expanding into asbestos. The committee will obtain direction from the NELAC BoD on this issue at the next BoD meeting.

Future plans include revision of Chapter 5 so that it is in agreement with ISO/IEC 17025 (by 3/19/01). Dr. Fred Siegelman is leading the effort. The committee plans to form a PBMS subcommittee, led by Mr. Siders (by 11/00). The microbiology subcommittee will finalize proposed changes to Section D.3 (by 3/19/01). The committee will submit proposed language based on ELAB D.1 comments (by 3/19/01). The committee will obtain additional direction from the Board on ISO 17025 as needed.

Accrediting Authority – Chair: Mr. John Anderson

One of the main issues for the committee was assuring uniformity of accrediting authority assessments for NELAP recognition. This included: documentation, checklists, assessor qualifications, and assessor training. Other issues were recognition of non-NELAP accrediting authorities and standards interpretation dispute recognition (mechanism for laboratory appeal). Mr. Anderson said that the committee has had excellent discussion with lots of good comments and suggestions from participants.

Future plans are to develop a questionnaire for determining main concerns about uniformity issues (by 1/1/01), begin discussion of issues raised at the committee meeting (by 12/15/00), and develop a conceptual proposal to address issues (by 3/15/01).

Field Activities – Chair: Mr. Dan Bivins

Highlights of the committee meeting included presentation of a general sampling standard (withdrawn last year due to copyright issues), media-specific sampling standards, and a draft proposal of "General Requirements for the Competence of Air Source Emission Testing Bodies" submitted by the Air Source Emission Task Team (ASETT), a subcommittee of ELAB. A copy of the September 19, 2000, ASETT proposal (version 1.1) was included in participant packets. Mr. Bivins said that the committee needs to discuss the ASETT proposal and put together comments (by 1/19/01).

Field sampling as a field of testing is an unresolved issue, as well as definitions for "field measurements" and "mobile laboratories" (committee will work with Accreditation Process Committee). The committee plans to take action on these by January 19, 2001. They will also continue to work on media-specific sampling standards (meet with accrediting authorities to determine how to proceed and which ones to include).

Future plans are to meet with accrediting authorities to discuss scope of accreditation for sampling (by 2/01), submit changes to the Program Policy and Structure Committee for fields of testing structure (by 2/01), meet with the Accreditation Process Committee on definitions (by 1/01).

Regulatory Coordination – Chair: Dr. Carl Kircher

Highlights of the committee meeting included discussion about the NELAP Scope of Accreditation and PT Field of Testing, review of the semiannual EPA Regulatory Agenda, and presentation of a revised Model Administrative Rules for comment. The Model Administrative Rules were changed to be consistent with the straw poll taken at the last meeting, but will be revised again when the Scope of Accreditation and PT Field of Testing are defined. This revised model should be posted on the NELAC Website by January, 2001.

The model regulations for handling secondary accreditation, reporting, and accreditation renewal are still unresolved. The committee plans to take action by January, 2001. They also plan to review the October 2000 EPA Regulatory Agenda by March, 2001.

Membership and Outreach – Chair: Ms. Marge Prevost

Highlights of the committee include a review of the website content and improvements such as completion of a site map and a status report tool (pop-up menu) for identifying new information posted on the internet.

Ms. Prevost said that the mission of the Membership and Outreach Committee is to communicate information to members of NELAC, the public, and the regulatory community. The main vehicle of communication will remain the website, but the committee will focus on identifying additional channels. Possible outreach vehicles include "list serve" for information updates and development of hard copy briefing materials (e.g., brochures, pamphlets, posters). The committee will also try to identify publicity vehicles for the announcement of initial NELAP-

accredited laboratories. The committee will investigate the feasibility of these ideas and the availability of resources.

Nominating Committee – Chair: Dr. James Pearson

Dr. Pearson said that the committee has received several nominations. One member is rotating off the committee and the committee needs to nominate a new chair-elect. Dr. Brokopp added that there is currently a vacant position on the committee. Participants were asked to inform the Nominating Committee if there are additional nominations.

National Database – Chair: Mr. Matt Caruso

A presentation was given by the database contractor during the committee session. Mr. Caruso said that the NELAP National Database is currently in its testing phase which is scheduled to continue for the next two months. The transition from development to deployment is scheduled to be complete by January, 2001. The committee will continue to assist the database contractor and EPA through the transition phase.

Mr. Caruso said that there are no unresolved issues, provided that the Scope of Accreditation remains defined by three elements. Therefore, the database design can accommodate "program-method-analyte" (as defined in the 1999 NELAC standards) or "matrix-method-analyte" (possible change for 2001?).

Transition – Co-chair: Ms. Silky Labie

Some of the issues the Transition Committee is addressing include: uniformity of laboratory assessments and accrediting authorities, secondary accreditation (recognition and requirements), confusion on how to handle non-detects, and implementation dates. With respect to implementation dates, states are allowed two years to implement changes to the standards because of their regulatory process. The committee proposes that if a shorter time period is required, a different time frame may be attached to revised standards for vote.

To increase uniformity, the committee plans to explore ways of facilitating communication and monitoring progress. Some of the current ideas include: a hot line for complaints, surveys, a review of accreditation packages, forum or teleconference, establishment of standard operating procedures for accreditation and laboratory evaluation, and a review of other models which are being used to evaluate assessors. This work will begin immediately and continue on an ongoing basis.

Related to secondary accreditation, the committee will try to identify requirements and ensure that no certification/accreditation lapses before NELAP accreditation is granted (by 12/00). The committee will look at the issue of non-detects, which is close to resolution (by 12/00). They will also will consider whether the standards can be published less frequently to help with implementation (by 3/01).

CLOSING PLENARY SESSION

Dr. Charles Brokopp began his closing remarks by thanking the staff from Research Triangle Institute (RTI) for their ongoing support which allows the meetings to run more productively and efficiently. He then offered participants another opportunity to voice questions directed to the committee chairs. No questions were offered. Dr. Brokopp thanked everyone for their participation and input.

Dr. Brokopp thanked the many organizations involved for their ongoing support. Especially the following:

- EPA Office of Research and Development, Mr. Henry Longest, Dr. John Lyon, Dr. Steve Billets, and Ms. Jeanne Hankins
- NELAC Board of Directors
- NELAC Committees and Chairs
- Collaborating organizations such as EPA Regional Offices
- Environmental Laboratory Advisory Board, especially Dr. Wilson Hershey (Chair)
- ELAB PBMS subcommittee

He said that during the last few days, many issues have been raised. In January 2001, NELAC will begin recognizing the first accredited laboratories. He said that we have worked long and hard to achieve this accomplishment. Years of persistence and hard work have fostered cooperation between states, federal agencies, and other organizations. He said that the states have contributed significantly and that NELAC could not have achieved this success without the support of industry (e.g., laboratories, PT providers).

Dr. Brokopp announced that NELAC is successful. It is a benefit to stakeholders, to accrediting authorities, and to consumers who will now have access to consistent laboratory quality. NELAC will continue to move forward and will be a powerful organization. NELAC is needed by federal and state environmental accrediting authorities. Dr. Brokopp said that he is looking forward to recognizing additional accrediting authorities. He said that we need to expand on all levels. For example, the use of ANSI/ISO standards, accommodation of PBMS, and consistent laboratory audits. He said that we need to get NELAC operational with a high degree of credibility. With continued help and support, we will succeed. He ended by saying that he looked forward to seeing participants in May 2001 at Salt Lake City, Utah.

NEXT STEPS

Ms. Jeanne Hankins spoke about NELAC's next steps. She said that we need to find a long term solution to including ISO language in the NELAC Standard. Usage of the ISO language currently costs $25,000 per year, and will not be allowed after three years since the International Organization on Standardization is also opposed to free access of ISO language on the internet.

Ms. Hankins asked participants to get their comments to the committees no later than January 19, 2001. She noted that NELAC is considering options for co-sponsoring the interim meetings. This may include some changes in format. ELAB is considering further interactions with EPA National Program Offices. They want to expand outreach to other states to encourage the states to become accrediting authorities. The EPA Regional Offices are working now to make sure that they consistently respond to the two-year renewal period for NELAP Accrediting Authorities. Ms. Hankins said that NELAC will look at secondary accrediting authorities' plans and try to include them in the NELAC program. She said that she would like to see the secondary accrediting authorities become primary accrediting authorities. She asked participants to contact her or Dr. Brokopp if they have suggestions for further actions. In closing, she reminded participants of the ELAB open forum, immediately following the closing plenary, and the ELAB meeting at 9:00 a.m. on Friday, November 3, 2000.

Attachment A
PBMS Activities and Perspectives

Performance Based Measurement Systems

Activities and Perspectives

NELAC VIi
November 2000

PBMS Agenda

EPA Activities to Establish PBMS
Jerry Parr, Catalyst Information Resources / ELAB

A State Perspective
Ann Marie Allen, Massachusetts DEP

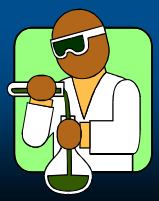
A Perspective from Industry
Dr. Harry Gearhart, DuPont / ELAB

A Laboratory Perspective
Deborah Loring, STL

An Instrument Manufacturer's Perspective
Elaine A. LeMoine, PerkinElmer Instruments / ELAB

Implementation Straw Model
ELAB Subcommittee

Discussion



EPA Activities to Establish PBMS

Jerry Parr
ELAB

PBMS Implementation

- **Directive from EPA Deputy Administrator Fred Hansen that Agency will adopt PBMS by the end of 1998**
- **Each Agency AA had to develop a PBMS Implementation Plan by September, 1997**
- **FRN published on October 6, 1997 (62 FR 52098) announcing EPA's intent to implement PBMS across all Agency programs**

Implementation Efforts

- **OAR**
- **OSWER**
- **OW**
- **OPPTS**

OAR Plan

- **Measurement Requirements / Methods Eliminated from PBMS Consideration:**
  - **Method–defined**
  - **Sampling Requirements (also method–defined)**
  - **Policy considerations**
- **PBMS Compatible Measurement Requirements / Methods Ranked according to difficulty in making regulatory revisions**

Oar Highlights

- Performance–based requirements with retention of up-front approval process:
  - Ambient Monitoring Program
  - Acid Rain Program
  - Engine and Vehicle Programs
- PBMS rulemakings planned:
  - Fuels Program
  - Radiation Program
  - Stationary Source Program
- No action planned
  - Indoor Air Program

OSW

- Believe PBMS already exists
- Remove unnecessary requirements to use SW-846 methods from RCRA regulations
- Incorporate DQOs directly into RCRA regulations
- Provide training

40 CFR 261.38 Comparable Fuel Exclusion

- Generator may use any reliable analytical method
- Responsibility of the generator to ensure that the sampling and analysis are unbiased, precise, and representative
- Demonstrate that each constituent is not present above the 95% upper confidence limit around the mean
- Burden of proof is on the generator

PBMS in EPA's Office of Water

PB **Method** S

OW Approach

- Use any validated method that meets performance criteria
- No EPA approval
- Criteria are those in Reference Methods
- Not applicable to method-defined analytes
- Optional state implementation

OW Method Validation

- 3 tiers
  - single facility
  - single matrix type
  - nationwide
- MDL, IDC
- On-going QC

The First Example:Method 1631

- Atomic Fluorescence
- Mercury at low ppt levels
- Promulgated June 8, 1999

PBMS in Method 1631

- Meet criteria in method
- Cannot lower MDL/ML
- Cannot use data if QC not achieved

Method 1631 QC Limits

- IPR
  - Precision 21
  - Recovery 79-121
- OPR
  - Recovery 71-125
  - RPD 24
- MDL
  - </= MDL (0.2 ng/L), or
  - < 1/3 RL

Other Requirements

- Documentation
- Raw Data
- "Changes in the principle of the determinative technique are not allowed"
- "If an analytical technique other than the technique specified in this Method is used, that technique must have a specificity for mercury equal to or better than the specificity of the technique in this Method"

Method Performance vs Data Needs

- PMI Regulation (40 CFR 439)
- PMI Methods (40 CFR 136)
- PMI QC Requirements (Method 1666)

PMI Regulation and RM Requirements

Analyte	RL	ML	IPR
Ethyl acetate	1.3	0.010	60-157
Ethanol	10.0	20.0	66-130
Isopropanol	3.9	0.20	d-418
Methanol	10.0	50.0	57-109
Dimethyl Sulfoxide	91.5	100	70-130

Conclusion

- EPA management is committed to the Performance Based approach to monitoring
- Work still needs to be done and many implementation issues need to be resolved
- Efforts are behind schedule

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A State Perspective

Ann Marie Allen
Massachusetts Department of Environmental Protection

PBMS: A State Perspective

- STAKEHOLDERS
  - State Laboratory
  - Laboratory Accreditation Program
  - Municipal and Commercial Laboratories
  - State Programs Using Data
  - USEPA & Other Federal Agencies

Advantages Of PBMS

- Scientifically & Technically Sound
- Freedom & Flexibility for Technical Improvements
- Quicker Implementation of New Techniques

Advantages Of PBMS (cont.)

- Accelerated Method Approval
- Encourages Communication Among Producers and Users of Data

Challenges Of PBMS

- Encourages Communication Among Producers & Users of Data
- PBMS Not Clearly Defined
- Changes in Roles & Responsibilities
- Proficiency Tests
- Requires New Approach to Data Audits

Challenges Of PBMS (cont.)

- Cost
- Enforcement
  - Data Validity & Defensibility
  - Data Comparability
  - Cutting Costs or Cutting Quality

Challenges Of PBMS (cont.)

- Education Required
  - Laboratory Personnel
  - Laboratory Assessors
  - Data Evaluators and Data Users
- Step-wise Approach Needed

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Performanced Based Measurement Systems A Perspective From Industry

Harry L. Gearhart
DuPont - ELAB

Current Status Of PBMS

- PBMS currently characterized more as a concept than a defined program
- States' approach to PBMS largely undefined
- NELAC Standards flexible for incorporation of PBMS
- Widely differing understanding of PBMS among and between the various stakeholder groups

Issues/concerns Re PBMS Implementation

- Specific Agency guidance is needed for operational implementation of PBMS DQO's and MQO's
- Additional guidance is needed for method and data validation and lab accreditation
- PBMS will increase demands for skilled technical resources by agencies, industry, laboratories, etc
- Common concerns voiced on comparability and defensibility related to non-EPA methodologies
- Cost benefits are yet to be demonstrated

Comments For Successful Implementation Strategy

- PBMS will be successfully implemented via transition rather than step change
- EPA published methods will continue to serve many regulatory needs
- Method modification/development will appropriately handle cases where technology gaps exist re DQO's and MQO's
- PBMS will be facilitated by partnering approach between agency, industry, laboratory, validator, and instrument manufacturer groups via NELAC

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A Laboratory Perspective

Deborah Loring
STL

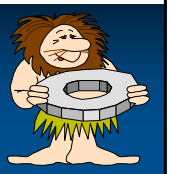
Advantages Of PBMS

- Up-front planning with client & regulator
- Project based, common sense approach
- Eliminate unnecessary conflicts in QC requirements
- Allows laboratory scientists to participate in solving environmental problems
- New Technology
- Reduce data misrepresentation issues
- Can help labs become more competitive

Challenges Of PBMS

- Translating DQOs into laboratory methods
- Personnel
- Investment in communication tools
- Auditing
- Results are subject to technical interpretation

Historical Example - 1994



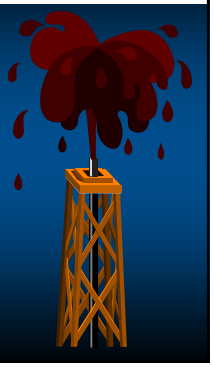
- RCRA Site
- Contract Laboratory Protocol
- 24-48 Hour TAT
- 175 Soils/75 Groundwaters over 5 weeks
- Volatiles, Semivolatiles, Metals (no Hg)

Volatiles & Semivolatiles (OLM1.0)

Method Element	*Modification*
Tune	No change
Initial Calibration	No change
Continuing Calibration	No change
Method Blank	No change
Internal Standard Area	Rerun if necessary, based on professional judgement. Flag data if outside limits
Internal Standard Retention Time	No change
Surrogate Standard Recovery	Rerun if necessary, based on professional judgement. Flag data if outside limits
Dilutions	Dilute if detector is saturated

Volatiles & Semivolatiles (OLM1.0)

Method Element	*Modification*
GPC	Not Performed
TICs	Not Reported
MS/MSD	No Change
Reporting limits	No Change
Final value	Wet Weight



Metals (ILM2.0)

Method Element	*Modification*
Digestion	1 for ICP only (no Graphite Furnace)
IDLs	Raised for As, Se, Tl, Pb
Initial Calibration	No Change
Initial Calibration Verification	No Change
Initial Calibration Blank	No Change
Detection Limit Standard	No Change

Metals (ILM2.0)

Method Element	*Modification*
Continuing Calibration Verification	Allowed up to 85-115% (from 90-110%) if that element not detected in bracketed samples.
Continuing Calibration Blank	No Change
LCS/MS/MD	No Change
Final Values	Wet Weight

Deliverables

Cover Letter, Chain of Custody

Volatiles & Semivolatiles
Analytical Results Sheet
Surrogate, MS/MSD Recovery Report
Internal Standard Summary
Chromatograms

Metals
Analytical Results Sheet

Project Results

Cost Reduced 50% from "Traditional CLP"

- TAT of 24-48 Met in most cases
- Data of Known Quality Generated
- Results were supported with 10-20% "Traditional CLP" samples, no data discrepancies

Success Dependent upon:

- Participation in Planning Stage with Client and Regulator

- Clear Project Goals
- Modifications Recommended and Allowed
- Full QC showed Comparability of Results
- Client, Laboratory, and Regulatory Flexibility

Application to Other Programs

SDWA

- Drinking water metals
- Improvements to Method 524.2

NPDES Example

- 600 Series methods

Conclusion

- Many laboratories are capable and ready for PBMS
- Personnel are willing to assist clients, assessors and regulators in implementation
- Most PBMS approaches have been taken under RCRA programs
- Adaptation of CWA, SDWA and other programs to PBMS should be straightforward

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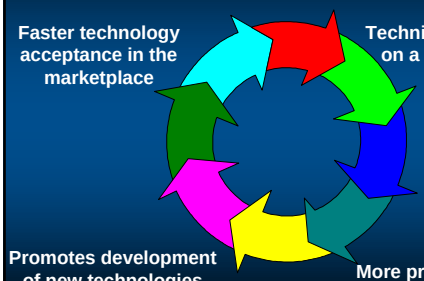
An Instrument Manufacturer's Perspective

Elaine A. LeMoine
PerkinElmer Instruments - ELAB

Instrument Manufacturers Perspective
New Technologies

- New technological developments offer laboratories quality and productivity improvements
  - Increased sensitivity
  - Increased accuracy
  - Faster through-put
  - Project appropriate technology
  - Operational savings
  - Higher return on investment

Instrument Manufacturers Perspective
Advantages to PBMS



Instrument Manufacturers Perspective
Disadvantages to PBMS

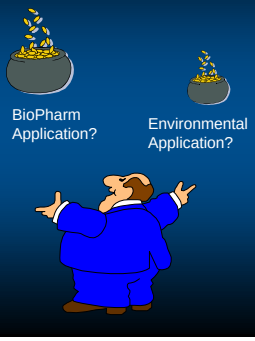
- Implementation between programs inconsistent
  - Must have predictable acceptance before investing in new technology development
- Additional vendor burden to provide more performance data

Instrument Manufacturers Perspective
Concerns

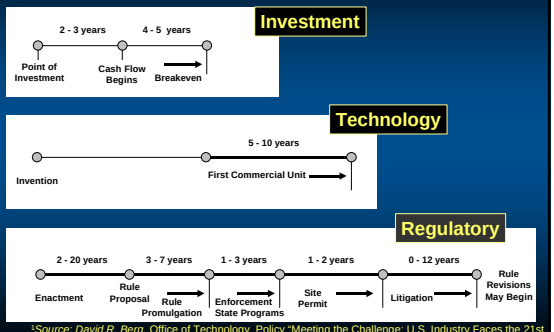
- Only a reasonable PBMS approach will encourage the development of new technology
  - Acceptance in a reasonable time frame
    - 6 months to 1 year
  - Widely accepted
  - Acceptance criteria well defined and clearly articulated
  - Flexibility tied to data quality objectives

Instrument Manufacturers Perspective
Investment Priorities

- Instrument manufacturers will only invest where they can get the best return for the shareholders
  - Method approval time
    - Environmental: ~10yrs.
    - Biopharmaceutical: <1 yr.
- PBMS provides more predictable and open market access
  - Investment choices become clear



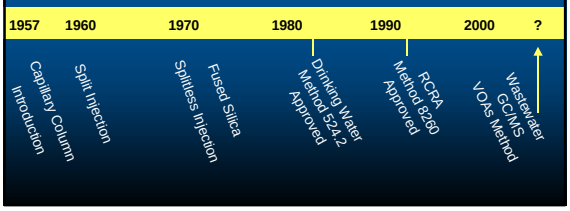
Incompatibility of Investment, Technology, and Regulatory Time Lines[1]



[1]*Source: David R. Berg,* Office of Technology Policy "Meeting the Challenge: U.S. Industry Faces the 21st Century, The U.S. Environmental Industry"

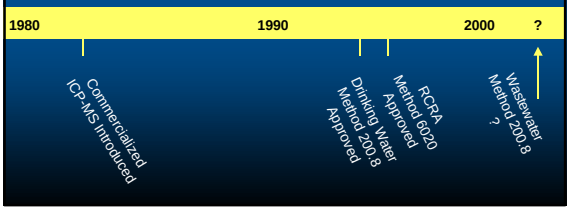
Instrument Manufacturers Perspective
Capillary Column Technology

- **Volatile Organics using GC/MS**
  - **Low level determinations**
  - **Wide range of analytes**



Instrument Manufacturers Perspective
ICP-MS Technology

- **Trace Metals**
  - **Higher sample through-put**
  - **Lower cost per analysis**



Instrument Manufacturers Perspective
Summary

- **Barriers to use of technological advances in the environmental field prevents the development of new technologies specific to this industry**
- **Widespread acceptance of innovative techniques promotes development of new technologies which stand to improve data quality, lab productivity and profitability**

Attachment B
PBMS Implementation Strawmodel

PBMS IMPLEMENTATION STRAWMODEL

NELAC

Environmental Laboratory Advisory Board

PBMS - A Straw Model

INTRODUCTION

STRAWMODEL PURPOSE

- **Provide conceptual framework to NELAC Quality Systems Committee for adaptation of NELAC PBMS Standards**
- **Facilitate progress toward uniform implementation within EPA Offices and Programs**
- **Facilitate implementation by States**
- **Provide communication among all stakeholders**

PRIMARY SOURCE MATERIAL FOR PBMS STRAWMODEL

- **Fred Hansen memo 6/11/97 to EMMC and EPA**
- **62 FR 52098 10/6/97**
- **EPA Offices PBMS Implementation Plans**
- **ELAB PBMS Report 1/99**
- **GIES PBMS Workshops Manual 1999**
- **ISO 17025**
- **CLP SOW ILM0.5**
- **NELAC Standards**

PBMS Definition

"a set of processes wherein the data quality needs, mandates, or limitations of a program or project are specified <by the Agency>, and serve as criteria for selecting appropriate methods to meet those needs in a cost effective manner"

2 FR 652098 10/6/97

EPA Intent for PBMS:

- **Replace existing alternative methods approval protocols**
- **Encourage use of new technology and method development**
- **Improve overall data quality**
- **Support regulatory mission**
- **Reduce costs**

2 FR 652098 10/6/97

PBMS *not* intended to:

- **Be wholesale replacement for use of current EPA methods**
- **Eliminate reference methods for compliance purposes**
- **Replace regulation method requirements (TCLP, BOD, etc)**
- **Get EPA out of method development/verification business**

2 FR 652098 10/6/97

Defining Characteristics of PBMS

Agency role:

- **Determine what constitutes an acceptable demonstration of compliance per program/project**
  - **Use regulation, QAPP, or permit process**
  - **DQO's will describe overall project needs, and will integrate considerations of risk, cost, and practicality**
  - **MQO's will consider capabilities of current methods based on demonstrated technology**

PBMS Characteristics, cont.

Regulated entity is responsible for:

- **Demonstration of regulatory compliance**
  - **Selects methods for compliance based on technical appropriateness**
  - **Evaluates, interprets, and reports results**

Unique characteristic:

- **Required measurement system performance is application-specific rather than method-specific**

PBMS - A Straw Model

PBMS STRAWMODEL

I. **Method selection**
II. **Method verification**
III. **Method modification**
IV. **Method development/validation**
V. **Data assessment & evaluation**

I. METHOD SELECTION -Concepts-

- Address client/agency requirements
  - prior client approval
  - demonstrate compliance; usable data
  - auditable/enforceable, etc
- Utilize available and/or appropriate technology
- Provide reliable, comparable results
- Be manageable and cost effective for agencies, regulated entities, and labs

METHOD SELECTION -*Proposed Hierarchy*-

1. Regulation specific methods
2. Program "reference" methods
3. Program "guidance" methods
4. Consensus organization methods
5. Method modification
6. Method development (new)

II. METHOD VERIFICATION -Concepts-

- Laboratory must perform and document initial and ongoing method verification steps for all methods for each representative matrix type
- Laboratory must perform and document routine/periodic Data Quality Indicator verification steps
- NELAC & agency input needed for DQIs and acceptance criteria

METHOD VERIFICATION -Elements-

- Initial demonstration by analyte
  - detection limit
  - accuracy and precision
  - representative matrix
- Continuing demonstration
  - accuracy and precision
  - representative matrix

Method Verification Elements, cont.

- Method (type) specific data quality indicators (DQIs) CLP ILM0.5
  - analyte specific calibration
  - sensitivity & range
  - instrument setup
  - parameter identification criteria
  - sample matrix specific QC (MS/MSD/REP & surrogates, as approp.)
  - method blank
  - periodic P. T.'s. by matrix type

Method Verification Elements, cont.

- EPA published container, hold time & preservative requirements will be applied by individual analyte or appropriate chemical classification
- Existing method criteria for DQI's will apply
- Matrix specific criteria will be established by the DQO process

III. METHOD MODIFICATION -Concepts-

- Client specific review/approval must occur before implementation
- Lab must document for NELAC, client, or agency:
  - method modifications in SOP format
  - modified methods listed in scope of services
  - modified methods referenced in reports

METHOD MODIFICATION -Elements-

- Modification is done primarily to:
  - add analytes
  - improve performance (e.g. sensitivity, recovery, etc)
- Modification would not select a new "determinative" assay step
- Lab must implement and document all applicable Method Verification elements

IV. METHOD DEVELOPMENT -Concepts-

- New method development may be done to:
  - support a specific client project need
  - support a specific or general Program need
  - offer new, generally applicable technology
- New methods require a more robust validation & documentation process, depending on scope of applicability
- Implementation invokes Method Verification steps

METHOD DEVELOPMENT -Elements-

- New method implementation must be pre-approved by the client
- New methods generally involve:
  - application of alternative technology in the "prep." or "determinative" step of the assay
  - determination of new analyte classes of interest
  - major improvement in instrument design/performance

Method Development Elements, cont.

- Method validation model is dependent on scope of application
  - single lab-single client
  - single lab-multiple clients
  - multiple labs-multiple clients
- Method validation models have been documented by EPA, GIES, ASTM, and others

V. DATA EVALUATION & ASSESSMENT -Concepts-

- Assessment is an important aspect in determining data usability
- Data assessment is the process of comparing project objectives and measurement objectives with the set results generated
- Data assessment is an attribute of PBMS, but not unique to it

DATA EVALUATION & ASSESSMENT -Elements-

- Laboratory is responsible to:
  - adhere to Method Verification steps to generate sample test results
  - report matrix related QC results
  - report exceptions to the above
  - provide/maintain supporting documentation for audit and/or review
- Client is responsible for overall data review

DATA EVALUATION & ASSESSMENT -Elements-, cont.

- NELAP contributes to the process with certification standards which define the overall laboratory quality systems
- Agency assessment role is facilitated by standard approach

STRAWMODEL SUMMARY

- Presents a practical solution to program or project based method selection
- Provides definition through method selection hierarchy
- Addresses method verification, modification, validation, assessment and documentation

SUMMARY, Cont.

- Recognizes regulatory role of agencies and works within existing program formats
- Addresses new method/technology approval
- Based on principles from primary EPA reference material
- Incorporates fundamental elements from ISO 17025, GIES, ASTM, MDCB

ACTION ITEMS

NELAC
STATES
PRIVATE SECTOR
EPA

PBMS ACTION ITEMS

- NELAC
  - ELAB
    - present a workable implementation strawmodel
    - collaborate with EPA to train stakeholder groups on PBMS implementation principles
  - Quality Systems & ELAB
    - refine NELAC Standards, Ch. 5 to incorporate PBMS model
  - Program Policy & Structure
    - review/revise scope of accreditation definition
    - review/revise methods definition

PBMS ACTION ITEMS, Cont.

- **States**
  - **participate in NELAC process to develop standards**
  - **progress on regulatory issues *re* PBMS implementation**
  - **provide auditor training**

PBMS ACTION ITEMS, Cont.

- **Private Sector**
  - **develop adequate standard reference materials**
  - **pursue applications of new analytical technology**
  - **apply NELAC standards for new method validation**
  - **apply NELAC standards for method verification**

PBMS ACTION ITEMS, Cont.

- **EPA:**
  - **regulatory activities:**
    - **define data quality indicators (performance characteristics) by method type**
    - **determine achievable acceptance criteria based on robust multiple-lab studies**
    - **modify regulations to facilitate PBMS**
  - **continuing activities:**
    - **pursue method development role**
    - **formally endorse NELAC/NELAP**
    - **participate in NELAC to define a comprehensive PBMS model for States to emulate**

CONCLUSION

- **PBMS Strawmodel presented at NELAC InterimVI by ELAB for input**
- **Strawmodel being considered by EPA, NELAC, and other Stakeholders**
- **Quality Systems & Prog. Policy & Structure Committees will propose Standards language at NELAC VII**

ACKNOWLEDGEMENTS

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Alice Wusterhausen, STL Inc.

PBMS Subcommittee Members
ELAB Members